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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/853,193

05/11/2001

Greta Van Den Berghe

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04/24/2006

NOVO NORDISK, INC.  
PATENT DEPARTMENT  
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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/853,193

Applicant(s)

VAN DEN BERGHE, GRETA

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-36, 40-44, 62-71 and 86 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 32-36, 40-44 and 62-71 is/are allowed.  
6) ☒ Claim(s) 86 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 32-36, 40-44, 62-71 and 86 are pending.

Applicant's amendment and response filed February 21, 2006 is acknowledged, and applicants' response has been fully considered. Claims 1, 22 and 23 have been amended, claims 1, 4, 7-14, 22-29, 37-39, 45-61 and 72-85 have been cancelled, and a new claim 86 has been added. Therefore, claims 32-36, 40-44, 62-71 and 86 are examined.

### **Withdrawn Claim Rejections - 35 USC § 112**

2. The previous rejection of claims 4, 7-14, 47-61 and 74-85 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's cancellation of the claim, and applicant's response at page 5 in the amendment filed February 21, 2006.

### **Withdrawn Claim Rejections - 35 USC § 102**

3. The previous rejection of claims 1, 22-28, 37-39, 45-46 and 72-73 under 35 U.S.C. 102(b) as anticipated by Malmberg *et al.* (J. Am. Coll. Cardio. 26, 57-65 (1995)), is withdrawn in view of applicant's cancellation of the claim, and applicant's response at page 5 in the amendment filed February 21, 2006.
4. The previous rejection of claims 4, 7, 12-14, 52-54, 60, 61, 84 and 85 under 35 U.S.C. 102(b) as anticipated by Shangraw *et al.* (Metabolism 38, 983-989 (1989)) as evidenced by Van Den Berghe (US 2002/0107178), is withdrawn in view of applicant's cancellation of the claim, and applicant's response at pages 5-6 in the amendment filed February 21, 2006.

***Claim Objection***

5. Claim 86 is objected to because of the use of the term "ahuman" in line 1. Appropriate correction is required.

***New Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 86 is rejected under 35 U.S.C. 102(b) as being anticipated by Scott *et al.* (Stroke 30, 793-799 (1999), in IDS filed February 12, 2002).

Scott *et al.* teach the use of a 24-hour infusion of saline (control) or a glucose potassium insulin (GKI) infusion (including 16 U of human soluble insulin, 20 mmole of KCl in 500 ml 10% dextrose) at 100ml/h in the treatment of 53 acute stroke patients with mild or moderate hyperglycemia (plasma glucose between 7.0 and 17.0 mmole/L, corresponding to 126 and 307 mg/dL) in an explanatory, randomized, controlled trial to test safety, where no statistically significant differences is detected between the two groups at baseline (Table 1), and the GKI group had lower mean plasma glucose levels at 8 hours (6.4 mmole/L, corresponding to 115 mg/dL), 16 hours (6.5 mmole/L, corresponding to 117 mg/dL) and 24 hours (6.9 mmole/L, corresponding to 124 mg/dL) from the time starting infusion as compared to control, and the mean plasma glucose level is 9.1 mmole/L at zero time of infusion, which corresponds to 164 mg/dL (Table 2; Fig. 1; pages 794-796; claim 86). The acute stroke patients with no diabetes

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mellitus in their medical history (Table 1) are human non-diabetic critically ill patients, which meet the criteria of the claimed invention.

### ***Conclusions***

7. Claim 86 is rejected; and claims 32-36, 40-44 and 62-71 are free of art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

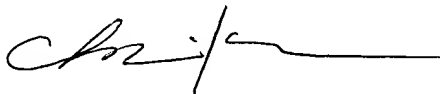
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

April 19, 2006